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10/783,522	02/20/2004	Roy Lurie	MWS-109RCE2	7481
74321 7590 04/27/2010 LAHIVE & COCKFIELD, LLP/THE MATHWORKS FLOOR 30, SUITE 3000 One Post Office Square Boston, MA 02109-2127				
EXAMINER				
WHALEY, PABLO S				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/783,522

**Applicant(s)**

LURIE ET AL.

**Examiner**

PABLO WHALEY

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-50 are currently pending. The restriction election for claims 37-50 is withdrawn due to lack of search burden. Claims 37-50 are hereby rejoined. Claims 1-50 are under consideration. Claim 51 is cancelled.

### ***Withdrawn Rejections***

The rejection of claims 1-36 under 35 U.S.C. 103(a) as being made obvious by Yao et al. (IEEE International Conference on Control Applications, Sept. 2000, p.1-21), in view of Rice et al. (US 2002/0091666, Published: July 11, 2002; Filed: July 2, 2001), and in view of Potts et al. (US 6,882,940; Filed Aug. 10, 2001) is withdrawn in view of applicant's amendment.

## **NEW GROUNDS OF REJECTIONS**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-14, 16-23, 25-30, 32-36 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004).

The amended claims are drawn to a computer-readable medium holding instructions executable in a computing device, the instructions when executed causing at least one computing device to: generate a result from executing a block diagram model of a biological process by performing a simulation of the block diagram model with a simulation engine; store a simulation context of the simulation by registering an area of memory that constitutes the simulation context, the simulation context comprising one or more values for one or more attributes, the one or more values being established during the simulation of the tile block diagram model; gather data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted; compare the generated result to the data gathered from the experimental device using an analysis environment that is in communication with the simulation engine; and modify the model of the biological process based on the comparison to correct the model of the biological process.

Lett teaches a method and system for incorporating image data into a biological simulation model [p.10-12]. In particular, time-series images of biological samples are obtained from experimental imagers [p.11-12], which is interpreted as gathering data from an in-situ experimental device since the data is

obtained over time. The acquired image data is transmitted to a computer comprised of a central processing unit (CPU), a user interface, and memory (including both primary random access memory (RAM) and nonvolatile secondary memory [p.12 and Fig. 1]. A simulation program generates predicted images, and these generated images are compared with acquired images [p.14]. The simulation model is then modified to improve the goodness of fit between predicted and obtained images [See at least p.14, last para., and p.24], which shows a modifying a model based on a comparison to correct the model. In particular, numerical intensity values are used to compare images [p.15], which is a teaching for values established during a simulation context. The simulation model is described according to a block diagram and is used to predict spatial distribution variables [See at least p.22 and Fig. 2], therefore Lett teaches an analysis environment for generating results according to a block diagram model. Image data can be obtained from a gene-chip and microarray data [Ref. claims 18, 19, and p.18]. The simulation model includes program code for performing the simulations [p.37]. Lett teaches calculating error measures that correlate with the difference between the predicted and acquired images are calculated [p.17].

Lett does not explicitly teach storing a simulation context of the simulation by registering an area of memory that constitutes the simulation context, the simulation context comprising one or more values for one or more attributes, the one or more values being established during the simulation of the tile block diagram model, as in amended claims 1, 12, 22, and 28. However, the entire simulation process taught by Lett is performed and stored on a computer [p.11-12], and calculates variables throughout the simulation process [p.22]. Therefore Lett implicitly teaches limitations drawn to storing a simulation context during the simulation of a block diagram model, as in amended claims 1, 12, 22, and 28.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004), as applied to claims 1-3, 5-14, 16-23, 25-30, 32-36

above, in view of Fox et al. (WO 03/042857, Published 22 May 2003; IDS filed 11/08/2004), and in view of Potts et al. (US 6,882,940; Filed Aug. 10, 2001).

The instant claims are drawn to a method and computer-readable medium holding instructions executable in a computing device, the instructions when executed causing at least one computing device for accessing a block diagram model of the chemical reaction, generating a result from executing the model of the chemical reaction, gather data relating to an ongoing in situ experiment of the chemical reaction directly from an in situ experimental device, comparing the generated result to the data gathered from the experimental device using an analysis environment that is in communication with the simulation engine; and modifying the model of the chemical reaction based on the data relating to the ongoing experiment.

Lett makes obvious a method, device, and computer readable medium for simulating biological processes using a block diagram simulation model, as set forth above.

Lett does not specifically teach a method and computer readable medium for modifying a model of a biological process wherein the process is a chemical reaction, as in claims 37-39, 41-45, and 48-50.

Lett does not teach generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, as in claims 4, 15, 24, 31, 40, and 47.

Fox teaches a method and system for inferring biochemical interaction networks including chemical reactions from dynamical or static experimental data, and a database of possible interactions [0065]. The simulation process operates according to a block diagram and includes the use of threshold values [Fig. 7, Fig. 8].

Potts teaches a prediction system with a modeling environment that allows for user-settable threshold levels [Col. 13, lines 20-25] and functionality for generating an alert signal when a measured signal is outside of the predetermined range of values [Co. 7, lines 20-23].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and system made obvious by Lett by alternatively modeling a chemical reaction, as taught by Fox, since Lett suggests biological modeling software that models chemical reactions using experimental microscopic image data with predictable results [p.5, and p.7-9], and since Fox specifically employs a block diagram for simulating chemical reactions from experimental data [0065, Fig. 7, Fig. 8]. The motivation would have been to predict new interactions for the biological system being studied, as suggested by Fox [Abstract].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and system made obvious by Lett by generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, since Fox suggests the use of thresholds in a block diagram simulation process with predictable results, as set forth above, and since Potts employs software programming for generating an alert signals when signals are outside of threshold ranges with predictable results [Co. 7, lines 20-23]. The motivation would have been to improve simulation by generating warning messages when there are images with statistical differences between them, as suggested by Lett [p.15].

#### ***Response to Arguments***

Applicant's arguments filed 01/27/2010 that Yao, Rice, and Potts do not teach storing a simulation context of the simulation by registering an area of memory that constitutes the simulation context, the simulation context comprising one or more values for one or more attributes, the one or more values being established during the simulation of the tile block diagram model, as in amended claims 1, 12, 22, and 28, have been fully considered but are moot in view of the new grounds of rejections.

#### ***Provisional Obviousness-Type Double Patenting Rejection***

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise

Art Unit: 1631

extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1, 12, 22, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 3 of copending Application No. 10/783552 in view of Rice. Both the instant claims and the copending claims recite limitations drawn to block diagrams, a simulation engine, and analysis environment. Although the conflicting claims are not identical, they are not patentably distinct from each other. In particular, the copending claims are drawn to simulations of a species of the instant claims, wherein the species "chemical reactions" are a species of biological process. Furthermore, while the copending claims do not recite gathering data from an in situ device, this limitation would have been obvious to one of ordinary skill in the art in view Rice, as set forth above. The motivation would have been to improve the knowledge of dynamic biological processes, as suggested by Rice [0008]. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

Applicant's statement in the response filed 01/27/2010 that a Terminal Disclaimer will be filed if necessary is acknowledged. However, as a Terminal Disclaimer has not been filed, this rejection is



maintained for the reasons set forth above.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Pablo S. Whaley**

Patent Examiner

Art Unit 1631

/PW/

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631

